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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,111	06/02/2000	Rory A.J. Curtis	MNI-062CP2DV1	6800

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LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/587,111

Applicant(s)  
Curtis

Examiner  
John Ulm

Art Unit  
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 12, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 22-45 is/are pending in the application.
- 4a) Of the above, claim(s) 1-19, 22-26, 28, 30, 38, and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 29, 31-37, 39, and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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1) Claims 1 to 19 and 22 to 45 are pending in the instant application. Claims 20 and 21 have been canceled and claims 27 to 45 have been added as requested by Applicant in Paper Number 10, filed 12 February of 2002. Claims 1 to 19 and 24 to 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

2) Newly submitted claims 28, 30, 38, 40, and claims 32 to 36 and 42 to 45 in so far as they depend from any of claims 28, 30, 38, 40, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

A polypeptide comprising the amino acid of SEQ ID NO:5 and a polypeptide comprising the amino acid sequence of SEQ ID NO:20 are two different proteins which lack unity of invention because they lack a common utility which is based upon a shared structural feature lacking from the prior art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28, 30, 38, 40, and claims 32 to 36 and 42 to 45 in so far as they depend from any of claims 28, 30, 38, 40, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

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4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) Applicant is advised that 37 C.F.R. § 1.821(e) only relates to computer readable forms of a sequence listing. Applicant is required to provide a paper copy of a sequence listing in each application disclosing an amino acid or nucleotide sequence in accordance with 37 C.F.R. § 1.821-1.825.

6) Claim 31 and 41, as well as claims 32 to 36 and 42 to 45 in so far as they depend from either of claims 31 and 41, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the practice of a method of identifying a ligand which binds to a receptor protein comprising the amino acid sequence presented in SEQ ID NO:5 of the instant specification, does not reasonably provide enablement for the practice of a binding assay which employs a protein having anything less than the entire amino acid sequence presented in SEQ ID NO:5 for those reasons of record as applied to claims 20 and 21 in section 5 of Paper Number 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has traversed this rejection on the premise that the instant specification provides the guidance needed to predictably alter SEQ ID NO:5. Those portions of the specification identified by Applicant as providing this guidance does not. The instant specification specifically identifies notable structural features of a protein of the instant invention.

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It neither provides the identification of the expendable residues in SEQ ID NO:5 nor even a single working example of a functional protein lacking its entire native amino acid sequence.

Applicant has cited a plurality of patent documents in traversal of this rejection. Applicant is advised that none of the patents cited were available at the time that the instant application was filed. As Applicant has pointed out, the instant application has an effective filing date of "**February 26, 1999**". With respect to the Silverman et al. publication, it simply shows that, given enough time and effort, one might be able to identify an agonist for a G protein-coupled receptor. However, such effort would require a substantial inventive contribution beyond the disclosure of the instant specification.

This rejection is further applied to claim 42. Claim 42 recites a binding assay which employs a yeast two-hybrid system. It was well known in the art prior to the time of the instant application that the yeast two-hybrid system can only employ small soluble proteins as shown in Figure 1 of the Chien et al. publication (P.N.A.S. 88:9578-9582, 1991). Therefore, one of ordinary skill in the art of molecular biology would immediately recognized that a yeast two-hybrid system which employed all of the amino acid sequence of SEQ ID NO:5 would be inoperative because the presence of the six transmembrane domains within that sequence (Figure 1B of Julius et al., Pat. No. 6,335,180) would generate an insoluble protein. In so far as this claim encompasses a system employing only a soluble portion of the amino acid sequence SEQ ID NO:5, the instant specification does not disclose a practical utility which is to be realized from the identification of a protein which binds to a portion of that amino acid sequence.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7) Claims 27, 29, 31, 37, 39, 41, as well as claims 32 to 34, 36 and 43 to 45 in so far as they depend from any of claims 27, 29, 31, 37, 39, 41, are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Julius et al. patent (6,335,180 B1). The amino acid sequence presented in SEQ ID NO:5 of the instant application is identical to the amino acid sequence presented in SEQ ID NO:36 of the Julius et al. patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8) Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Julius et al. patent (6,335,180 B1). Because the Julius et al. patent disclosed the fact that the receptor described therein was naturally expressed in neuronal tissue (first paragraph, column 37) an artisan would have found it prima facie obvious to have expressed that protein recombinantly in a neuronal cell line to obtain a more authentic response by that receptor to a test compound.

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9) Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Julius et al. patent (6,335,180 B1) in view of the Chien et al. publication (P.N.A.S. 88:9578-9582, 1991). To have incorporated portions of the capsaicin receptor of Julius et al. into the yeast two-hybrid system of Chien et al. to identify proteins with might interact therewith would have been *prima facie* obvious to one of ordinary skill in the art of molecular biology in view of this combination of references at the time that the instant invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800